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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,297	03/31/2004	Timothy James Jegla	018512-005920US	8561

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,297	JEGLA, TIMOTHY JAMES	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 12, 13 and 18 have been amended and claim 15 has been cancelled as requested in the amendment filed on June 05, 2006. Following the amendment, claims 12-14 and 16-18 are pending in the instant application.

Claims 12-14 and 16-18 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on June 05, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Information Disclosure Statement

5. IDS of March 31, 2004 stands non-compliant with 37 CFR 1.98(b)(5), see reasons of record in section 3 of Paper mailed on March 02, 2006. There appears to be no record of papers submitted with Applicant's reply, as stated by Applicant (middle at page 3 of the Response).

Claim Rejections - 35 USC § 101

6. Claims 12-14 and 16-18 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 5 of Paper mailed on March 02, 2006. Briefly, the instant

application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

The instant claims are directed to a polypeptide, which is asserted to be an alpha subunit of a novel voltage-gated potassium channel, Kv10 of SEQ ID NO: 3. However, the instant specification, as filed, fails to identify a specific biological significance of the instant polypeptide of SEQ ID NO: 3 and/or its association with any particular disease or pathological condition to substantiate the asserted therapeutic use of modulators of the polypeptide of SEQ IDNO: 3. Furthermore, there appears to be no evidence of record presented in the instant specification that would establish the significance of modulation of Kv10 of SEQ ID NO: 3 with relation to a specific physiological activity or a particular pathological condition. Thus, the instant specification, as filed, fails to provide any evidence or sound scientific reasoning to support a conclusion that "compounds that modulate Kv10 channels [...] can be useful as therapeutic agents for treating diseases related to altered functions in tissues expression Kv10 channels, such as disorders of the central nervous system" (page 6 of the Response). One skilled in the art readily appreciates that because the instant specification, as filed, has not linked the disclosed Kv10 with any specific disease state or disorder, including disorders of the central nervous system and male fertility (top at page 5 of the Response), there appears to be no scientific basis for concluding that a compound that modulates Kv10 would be useful for treating these diseases. One skilled in the art would be required to perform significant amount of further experimentation in order to identify a specific biological activity of Kv10, its significance to a particular disease

and, further, to what "use" any information regarding compounds that modulate Kv10 of SEQ ID NO: 3 could be put. For example, if a test compound was identified as being capable of inhibiting or activating Kv10 channels (by using "assays that involve measuring current, measuring membrane potential, measuring ion flux, or measuring patch-clamp electrophysiology" (bottom at page 5)), what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate the disease? Moreover, in the instant case, since the instant specification fails to present any evidence that Kv10 of SEQ ID NO: 3 is specifically associated with a particular pathological condition of central nervous system, retina or prostate, a skilled practitioner would not know which disease could be potentially treated by administration of a compound that is an agonist/antagonist of Kv10 of SEQ ID NO: 3.

In the absence of knowledge of the biological significance or relevance to a particular pathological condition of this specific Kv10 of SEQ ID NO: 3, there is no immediately obvious patentable use for it. Since the specification does not disclose a correlation between any disease or disorder and Kv10 of SEQ ID NO: 3, the results of screening for compounds that modulate influx of potassium through Kv10 would be meaningless without significant further research and considerable amount of experimentation. However, it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

Further, potential discovery of compounds that modulate potassium influx ("open or close of the Kv10 channels", p.5 of the Response) would not lead to prevention or treatment of a condition or disease as implied by the specification because without knowing functional

significance of Kv10 of SEQ D NO: 3 one would not expect that administration of a compound that "opens or closes Kv10" would have a considerable impact on the treatment of a disease. In other words, the specification does not disclose biological significance of Kv10 with respect to any disease, including diseases of the central nervous system and "abnormalities found in the retina (e.g., vision disorders) or prostate (e.g., male infertility)", p.5), as asserted in the instant specification. Thus, it is not a target for drug development for the pharmacology industry. Significant further research would have to be conducted to identify diseases or disease states which correlate with activity of the instant Kv10 of SEQ ID NO: 3.

At pages 6-7 of the Response Applicant argues that the instant specification presents evidence of record that "the Kv10.1 polypeptide can, when coupled with Kv2.1 or Kv2.2 subunit, form a functional heteromultimeric voltage-gated potassium channel. See Example 2 on page 63 of the specification. Applicant's assertion that Kv10.1 is a subunit of a voltage-gated potassium channel is therefore supported by experimental evidence". This argument has been fully considered but is not deemed to be persuasive for the following reasons.

The instant specification has provided a description of an isolated polypeptide and asserted that this polypeptide represents an alpha subunit of a novel potassium channel. To clarify the Examiner's position, there is no dispute that the novel disclosed amino acid sequence of SEQ ID NO: 3 could represent a subunit of a potassium channel. The importance of potassium channels in cellular physiology is well established. However, in the absence of knowledge of specific biological significance of this particular asserted alpha subunit of Kv potassium channel of SEQ ID NO: 3 the worker of skill in the art would not know how to use this instant novel polypeptide. Furthermore, because there is no information presented in the instant specification

or relied on in the prior art of record that would indicate that all members of potassium channels family are characterized by a unique common physiological function, disclosure of a novel sequence solely based on assertion that it belongs to the family of potassium channels is meaningless without clear understanding of how to use this particular polypeptide of SEQ ID NO: 3.

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

§101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form *Brenner*, 383, U.S. at 534-35, 148 USPQ at 695. *Brenner's* standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

In the instant case, Applicant's invention is predicated on the finding that a polypeptide of SEQ ID NO: 3 represents a novel potassium channel. Applicant further extrapolates this result into an assertion of usefulness of the disclosed polypeptide to treat "abnormalities found in the retina (e.g., vision disorders) or prostate (e.g., male infertility)". Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment and determine what is the biological significance of the instant novel potassium

channel, what physiological function could be regulated by changes in potassium influx associated with this channel, and then to assay for agonists or antagonists of this channel for their use as pharmaceuticals.

Therefore, since the instant specification does not disclose a credible "real world" use for the Kv10.1 polypeptide in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Applicant's reference to US application 09/833,466 has been fully considered (p.8 of the Response); however, it is well settled that the prosecution of one patent application does not affect the prosecution of another application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976). Accordingly, Applicant's arguments with respect to the patent 6,727,353 are unavailing.

Claim Rejections - 35 USC § 112

7. Claims 12-14 and 16-18 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

August 5, 2006

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